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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/780,318

02/17/2004

John Ellis

454313-2340.3

1114

7590

06/20/2006

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EXAMINER

CHEN, STACY BROWN

ART UNIT

PAPER NUMBER

1648

DATE MAILED: 06/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/780,318	ELLIS ET AL.	
	Examiner	Art Unit	
	Stacy B. Chen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 12-25 is/are pending in the application.
- 4a) Of the above claim(s) 1-8,13-16,20,21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9,12,17-19 and 22-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2/17/04; 5/31/06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's election with traverse of Group VIII, claim 12, is acknowledged. Applicant notes that in the restriction requirement, the Examiner required election of an additional pig pathogen from claims 15 and 21. Applicant points out that claim 12 does not recite additional pig pathogens. In response, the Examiner erred in requiring an election of an additional pig pathogen. In view of Applicant's amendments and arguments, claims 9, 12, 17-19 and 22-25 are pending and under examination.

With regard to the remainder of the restriction requirement, Applicant's arguments have been carefully considered. Applicant's substantive arguments are primarily directed to the following:

- Applicant argues that the Office's carving up of the claims is both inefficient and improper. Applicant points to MPEP 803.02 and 803.04, discussing Markush group practice and nucleotide sequences. Applicant argues that claim 9, as amended, recites a Markush group of only two nucleotide sequences, which is well within the 10 sequences deemed reasonable by the Commissioner. Applicant argues that a search for two nucleotide sequences would not be a serious burden.
- In response to Applicant's arguments, the Examiner maintains that the search and examination of more than one invention is a serious burden. The MPEP indicates that the search of more than nucleotide sequence is at the discretion of the Examiner. Regardless, because of the US Patent 6,943,152, the Examiner will rejoin SEQ ID NO: 4 and 13.

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- Applicant also argues Groups V-X are classified in the same class and subclass, further undermining the Examiner's position that a search of the claims within those groups presents a serious burden.
 - In response to Applicant's argument, the class and subclass classifications are not the only considerations for establishing burden of search.
- Applicant also argues that there is no undue burden in considering PCV-2 ORF4 and ORF13 together because the examiner of US Patent 6,943,152, considered two polynucleotides encoding the same two ORFs (ORF4 and ORF14). Applicant is mystified as to how it has suddenly become a burden in the instant application. Applicant argues that the two sequences are classified in class 435, subclass 5; they have not formed a separate status in the art; and the Examiner has not presented evidence of separate inventive effort by inventors, as mandated by MPEP 808.02(B). Applicant argues that there cannot be a separate field of search since it is not "necessary to search for one of the distinct subjects in places where no pertinent art to the other subject exists", as required by MPEP 808.02(C). Applicant reasons that there is simply no possibility that a proper search of a method for reducing viral load of PCV-2 by administering a composition comprising a vector containing and expressing a nucleotide sequence encoding one ORF would be found.
 - In response to Applicant's argument, as stated above, because of the US Patent 6,943,152, the Examiner will rejoin SEQ ID NO: 4 and 13 in order to maintain consistency.

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- Applicant also argues that there is not a substantial amount of art in this field at all, let alone prior art. Applicant argues that the present restriction should be redrawn such that Groups V-X, claims 9 and 12-25, already classified in the same class and subclass, are searched and examined together.
- In response to Applicant's argument, Groups V-X will not be rejoined in full. Claims 9, 12, 17-19 and 22-25 are rejoined together. The embodiments encompassing additional pig pathogens are not the same invention and will not be rejoined. Searching the claimed composition and additionally, another pathogen, would be serious burden of search.

Therefore, in view of the above, claims 1-8, 13-16, 20 and 21 are withdrawn from consideration, being drawn to non-elected subject matter. Claims 9, 12, 17-19 and 22-25 are examined on the merits. The restriction requirement is deemed proper and made FINAL.

Request for Clarification of the Claimed Invention

2. Applicant indicates that ORFs 1 and 2 of US Patent 6,943,152 are actually ORFs 4 and 13 of the instant application. Given that the '152 refers to ORFs 1-13, it appears that Applicant's use of their own terminology is minimally inconsistent between patent applications and misleading to public. Clarification is requested on this issue.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 9, 12, 17-19 and 22-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims refer to ORFs 4 and 13, which Applicant indicates are actually ORFs 1 and 2 of US Patent 6,943,152. Given the uncertainty of the identity of ORFs 4 and 13 of the instant application, Applicant is required to identify ORFs 4 and 13 by SEQ ID NO. The metes and bounds of the invention cannot be determined. This degree of identification will be useful for clarifying the claimed subject matter of the instant application.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 9, 12, 17-19 and 22-24 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 20-22 of U.S. Patent No. 6,497,883.

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Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented methods of inducing an immune response against porcine circovirus are performed with the same reagents as the instantly claimed methods of reducing viral load. The methods are obvious over each other because the method steps and reagents are materially the same.

Claims 9, 12, 17-19 and 22-24 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 22, 46 and 47 of U.S. Patent No. 6,943,152. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented methods of inducing an immune response against porcine circovirus are performed with the same reagents as the instantly claimed methods of reducing viral load, with the exception of an adjuvant. The methods are obvious over each other because the method steps and reagents are materially the same.

Conclusion

5. No claim is allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campbell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Stacy B. Chen 6/16/06

Stacy B. Chen
Primary Examiner
June 16, 2006